K011807

AUG - 7 2001

510(k) SUMMARY of Safety and Effectiveness

Sponsor:	OrthoTec, LLC 9595 Wilshire Blvd. Suite 502 Beverly Hills, CA 90212 Phone: (310) 557-2000 & (310) 273-1500 Fax: (310) 843-9500
Contact Person:	Patrick Bertranou, MD
Proprietary Trade Name:	SCS Claris Spinal Screws Types V, G and E
Device Description:	The SCS Claris Spinal Screws Types V, G and E are available in outer (major) diameters ranging from 5.5 to 9.5mm in 1mm increments and cancellous lengths ranging from 25 to 55mm in 5mm increments.
Intended Use:	**When used as a nonpedicle posterior system, the SCS system is indicated for patients with:** degenerative disk disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, deformities (i.e., scoliosis, kyphosis, lordosis), tumors, failed previous fusion (pseudarthrosis). **When used as an anterolateral/anterior system the SCS system is indicated for patients with:** degenerative disk disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, deformities (i.e., scoliosis, kyphosis, lordosis), tumors, failed previous fusion (pseudarthrosis) **When used as a posterior pedicle system, the SCS system is indicated for use in skeletally mature patients L3 and below who are:** having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint, receiving fusions using autogenous bone graft only, having the device fixed or attached to the lumbar and sacral spine, having the device removed after the development of a solid fusion mass. **Posterior pedicle systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:** degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, failed previous fusion (pseudarthrosis).
Materials:	The SCS Claris Spinal Screws are manufactured from stainless steel (ASTM F136 / ISO 5832-1) and titanium alloy (ASTM F138 / ISO 5832-3).
Substantial Equivalence:	Documentation was provided which demonstrated the SCS Claris Spinal Screws Types V, G and E to be substantially equivalent to the previously cleared SCS Claris Spinal Screws Types V, L and R. the substantial equivalence is based upon equivalence in indications/intended use, manufacturing methods, interconnection (attachment) mechanism, basic design and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 2001

Mr. Patrick Bertranou
President
OrthoTec, LLC
9595 Wilshire Boulevard, Suite 502
Beverly Hills, California 90212

Re: K011807
Trade Name: SCS Claris Spinal Screws Types V, G and E
Regulatory Class: II
Regulatory Number: 21 CFR 888.3070, 21 CFR 888.3050, 21 CFR 888.3060
Product Code: MNI, MNH, KWP, KWQ
Dated: July 23, 2001
Received: July 25, 2001

Dear Mr. Bertranou:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):_____

Device Name: ***SCS Claris Spinal System Screws***

Indications for Use:

When used as a nonpedicle posterior system, the SCS system is indicated for patients with:

degenerative disk disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
spondylolisthesis
fracture
spinal stenosis
deformities (i.e., scoliosis, kyphosis, lordosis)
tumors
failed previous fusion (pseudarthrosis)

When used as an anterolateral/anterior system the SCS system is indicated for patients with:

degenerative disk disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
spondylolisthesis
fracture
spinal stenosis
deformities (i.e., scoliosis, kyphosis, lordosis)
tumors
failed previous fusion (pseudarthrosis)

When used as a posterior pedicle system, the SCS system is indicated for use in skeletally mature patients L3 and below who are:

having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint
receiving fusions using autogenous bone graft only
having the device fixed or attached to the lumbar and sacral spine
having the device removed after the development of a solid fusion mass.

Posterior pedicle systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

degenerative spondylolisthesis with objective evidence of neurologic impairment
fracture
dislocation
scoliosis
kyphosis
spinal tumor
failed previous fusion (pseudarthrosis)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K011807